



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/122,427	7/24/1998	YIYU ZOU	UTSC584USC2	4389
7590	10/22/2003		EXAMINER	KISHORE, GOLLAMUDI S
PENNIE & EDMONDS LLP 1155 AVENUE OF THE AMERICAS NEW YORK, NY 10036-2711			ART UNIT	PAPER NUMBER
			1615	40
DATE MAILED: 10/22/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/122,427</b>	Applicant(s) <b>Zou</b>		
	Examiner <b>Gollamudi Kishore, Ph.D</b>	Art Unit <b>1615</b>		
<b>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</b>				
<b>Period for Reply</b> A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>three</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.				
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
<b>Status</b>				
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Aug 8, 2003</u>				
2a) <input checked="" type="checkbox"/> This action is <b>FINAL</b> .      2b) <input type="checkbox"/> This action is non-final.				
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.				
<b>Disposition of Claims</b>				
4) <input checked="" type="checkbox"/> Claim(s) <u>1, 3-9, 52-55, and 57-84</u> is/are pending in the application.				
4a) Of the above, claim(s) _____ is/are withdrawn from consideration.				
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.				
6) <input checked="" type="checkbox"/> Claim(s) <u>1, 3-9, 52-55, and 57-84</u> is/are rejected.				
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.				
8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.				
<b>Application Papers</b>				
9) <input type="checkbox"/> The specification is objected to by the Examiner.				
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.				
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.				
<b>Priority under 35 U.S.C. §§ 119 and 120</b>				
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).				
*See the attached detailed Office action for a list of the certified copies not received.				
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.				
15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.				
<b>Attachment(s)</b>				
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____		
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)		
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____		6) <input type="checkbox"/> Other: _____		

Art Unit: :1615

## **DETAILED ACTION**

**The request for the extension of time, filing under 1.114 and the preliminary amendment all dated 8-8-03 are acknowledged.**

**Claims included in the prosecution are 1, 4-9, 52-55, 57 and 59-84.**

### ***Claim Rejections - 35 USC § 112***

**1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

**2. Claims 1, 4-9, 52-55 and 66-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

**Lyophilization is a specific process which removes only water and volatile organic solvents. The independent claims 1 and 66 recite no water at all. These claims recites two components, namely, a lipid and a non-lipid surfactant. A review of the specification indicates the use of a phospholipid and a surfactant dissolved in t-butanol and water and the this product is then lyophilized. Since said claims are drawn to product by process, he examiner suggests reciting the process steps including t-butanol and water, a phospholipid and the surfactant.**

### ***Claim Rejections - 35 U.S.C. § 103***

Art Unit: :1615

**3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**4. Claims 1, 3-9, 52-55, 57 and 59-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta (4,950,432) or (5,811,119), further in view of Unger (5,585,112), Isliker (5,089,602), Hsu (5,653,996) individually or in combination.**

**Mehta discloses preliposomal powders containing a drug and a mixture of phospholipids. The process of preparation involves dissolving the lipid in t-butanol-water mixture and lyophilization of the mixture into a preliposomal powder. (note the abstract, columns 6-7, Examples and claims).**

**Mehta does not disclose the use of surfactants such as tweens in the preliposomal preparations.**

**Unger teaches that non-ionic detergents such as Tweens stabilize the liposome compositions (note col. 25, lines 38-48).**

**Isliker similarly teaches that Tweens could be used in liposome preparations; the liposome preparations are then lyophilized (Example 11).**

**Hsu teaches the use of Tweens in liposomal preparations (note col. 5, line 25 et seq.).**

**In essence, the secondary references all teach the routine practice in the art of the use of Tweens in liposomal preparations. Unger in particular teaches that these are**

Art Unit: :1615

**liposomal stabilizers. The use of Tweens in the preparations of Mehta would have been obvious to one of ordinary skill in the art since these are stabilizers and routinely used in the art in liposomal preparations.**

**Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that none of the references cited by the examiner disclose or suggest a lyophilizate with a lipid and a surfactant , which lyophilizate was made by lyophilizing the composition that did not contain liposomes at the time of lyophilization. The examiner disagrees. It is true that Mehta's compositions does not contain the surfactant during the lyophilization; but it is also true that Mehta's compositions also do not contain liposomes at the time of lyophilization. In response to applicant's arguments that in prior art, one must first make the liposomes and then use physical sizing methods, the examiner points out that instant claim language 'comprising' does not exclude these steps. That is why the examiner has suggested the use of 'consisting essentially of' during the interview in order to place the claims in condition for allowance and this is not done by applicant.**

**Applicant's arguments with regard to Unger that one of ordinary skill in the art would not be motivated to use sodium lauryl sulfate (SLS) are not found to be persuasive since instant claims do not recite any HLB criteria for the surfactant and the claim language 'non-lipid surfactant' does not exclude either cationic or anionic surfactants such as SLS taught by prior art.**

Art Unit: :1615

**Applicant's arguments with regard to Isliker and Hsu are not persuasive since these arguments once again are based on the physical sizing of the liposomes and as pointed out above, instant claim language does not exclude the physical sizing.**

**The examiner once again suggests, as suggested during the interview to recite the language ‘consisting essentially of’, recite the surfactant as ‘non-ionic surfactant’ and its ranges and complete process steps ( see 112 rejection above) in the independent claims in order to place the claims in condition for allowance.**

Art Unit: :1615

**5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.**

**The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.**

**If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.**

**Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].**

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

Art Unit: :1615

**Any inquiry of a general nature or relating to the status of this application should  
be directed to the Group receptionist whose telephone number is (703)308-1235.**



Gollamudi S. Kishore, Ph. D

**Primary Examiner**

**Group 1600**

*gsk*

**October 22, 2003**